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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/510,928	08/22/2005	Herbert O. Hultin	11944-006US1	4913

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EXAMINER	
GWARTNEY, ELIZABETH A	
ART UNIT	PAPER NUMBER
1794	

NOTIFICATION DATE	DELIVERY MODE
10/03/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PATDOCTC@fr.com

Office Action Summary	Application No.	Applicant(s)	
	10/510,928	HULTIN ET AL.	
	Examiner	Art Unit	
	Elizabeth Gwartney	1794	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-35* is/are pending in the application.

4a) Of the above claim(s) *29-35* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-35* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *20050914;20070213;20080228*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-28, drawn to a method of preparing an edible protein composition.

Group II, claim(s) 29-35, drawn to a protein composition.

2. The inventions listed as Groups I and II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

- The special technical feature of the invention of Group I is the addition of an amount of a polyvalent, food-grade cation which is not present in Group II.

3. During a telephone message from Attorney Todd Garcia on 09/03/2008 a provisional election was made without traverse to prosecute the invention of Group I, claims 1-28. Affirmation of this election must be made by applicant in replying to this Office action. Claims 29- 35 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

5. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Claim Objections

6. Claim 1 is objected to because of the following informalities:

- The term "protential" in line 2 appears to be a misspelling of the word ***potential.***

Appropriate correction is required.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claim 13 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 13 recites the limitation "sufficient acid" in line 1. There is insufficient antecedent basis for this limitation in the claim. Given that claim 13 depends from claim 12 and claim 12 includes a step of adding a ***base*** not an ***acid*** to the mixture, it is unclear what ***acid*** is being referred to in claim 13.

Further, the term “acid” renders claim 13 indefinite because it is unclear how an ***acid*** can be used to raise the pH of a mixture. Does applicant mean “base”?

To further prosecution, the term “acid” will be interpreted to read “base”.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

10. Claims 1, 3-9, 11-13, 17-25 and 27-28 are rejected under 35 U.S.C. 102(a) as being anticipated by Hultin et al. (WO 02/20720 A2) as evidenced by Merriam-Webster Online Dictionary ("incubate").

Regarding claim 1, Hultin et al. disclose a process of preparing an edible protein composition with reduced oxidation potential (i.e. undesirable components including membrane lipids are removed) from animal muscle (p.1/L5-6, 25-28), the method comprising:

(a) obtaining a mixture comprising water and minced or ground animal muscle (p. 2/L1-3, p. 10-14/Examples 1-3); and

(b) adding an aggregant, including calcium chloride and magnesium salt, to the mixture (p.3/L5-9, p.8/L8-12) thus,

(c) aggregating the membrane lipids and facilitating their removal (p.3/L5-9).

Given that Hultin et al. disclose adding calcium and magnesium salts (i.e. polyvalent cations) to the mixture, it is clear that the calcium and magnesium salts would inherently separate cellular membranes from cytoskeletal proteins in the animal muscle.

The recitation that said aggregating, i.e. "treating the mixture", step is to reduce the oxidation potential of the separated cellular membranes does not confer patentability to the claim since statements in the preamble reciting the purpose or intended use of the claimed invention which do not result in a manipulative difference between the claimed invention and the prior art do not limit the claim and do not distinguish over the prior art process. See, e.g., *In re Otto*, 312 F.2d 937, 938, 136 USPQ 458, 459 (CCPA 1963); *In re Sinex*, 309 F.2d 488, 492, 135 USPQ 302, 305 (CCPA 1962). If a prior art structure is capable of performing the intended use as recited in the preamble, then it meets the claim. See, e.g., *In re Schreiber*, 128 F.3d 1473, 1477,

44 USPQ2d 1429, 1431 (Fed. Cir. 1997) and cases cited therein, as it has been held that the recitation of a new intended use for an old product does not make a claim to that old product patentable. *In re Schreiber*, 44 USPQ2d 1429 (Fed. Cir. 1997). See also MPEP § 2111.02 and § 2112 - § 2112.02.

Regarding claims 3-4 and 24-25, modified Hultin et al. disclose all of the claim limitations set forth above. Hultin et al. also disclose treating the mixture by the addition an aggregant which causes one or more dispersed components of the mixture to aggregate (p.3/L5-9) and centrifuging or filtering (i.e. dewatered - p. 6/L27-p.7/L4, 14-23). The recitation that said aggregating step is to reduce the total separated membrane surface area does not confer patentability to the claim since statements in the preamble reciting the purpose or intended use of the claimed invention which do not result in a manipulative difference between the claimed invention and the prior art do not limit the claim and do not distinguish over the prior art process. See, e.g., *In re Otto*, 312 F.2d 937, 938, 136 USPQ 458, 459 (CCPA 1963); *In re Sinex*, 309 F.2d 488, 492, 135 USPQ 302, 305 (CCPA 1962). If a prior art structure is capable of performing the intended use as recited in the preamble, then it meets the claim. See, e.g., *In re Schreiber*, 128 F.3d 1473, 1477, 44 USPQ2d 1429, 1431 (Fed. Cir. 1997) and cases cited therein, as it has been held that the recitation of a new intended use for an old product does not make a claim to that old product patentable. *In re Schreiber*, 44 USPQ2d 1429 (Fed. Cir. 1997). See also MPEP § 2111.02 and § 2112 - § 2112.02.

Regarding claim 5, Hultin et al. disclose all of the claim limitations set forth above. Hultin et al. further disclose removing the membrane lipids from the mixture by filtration, addition of an aggregant, or centrifugation (p.3/L5-9, p.6/L 27-29).

Regarding claim 6, Hultin et al. disclose all of the claim limitations as set forth above. Hultin et al. also disclose aggregating the membrane lipids by adding an aggregant to the mixture and increasing the pH of the mixture to solubilize the animal muscle protein (p. 3/L5-12). Given that to incubate means "to cause or aid the development of", it is clear that adding an aggregant to the mixture to aggregate the membrane lipids is equivalent to incubating the mixture to allow the membrane lipids to aggregate (as evidenced by Merriam-Webster Online Dictionary – definition 2).

Regarding claims 7-8, Hultin et al. disclose all of the claim limitations as set forth above. Hultin et al. also disclose removing the aggregated separated membrane lipids from the solubilized protein by centrifugation or filtration and collecting the solubilized protein (p.6/L27-29, p.7/L14-23, p.8/L13-p.9/L22).

Regarding claims 9 and 11, Hultin et al. disclose all of the claim limitations as set forth above and that the step of further treating the mixture comprises adding an acid to the mixture to lower the pH to 2.5-3.5 (p.3/L13-16, p.8/L23-28).

Regarding claims 12-13, Hultin et al. disclose all of the claim limitations as set forth above wherein the step of adjusting the pH comprises adding polyphosphate to the mixture to obtain a pH of about 10.0 or above (p.3/L10-12).

Regarding claims 17-18, Hultin et al. disclose all of the claim limitations as set forth above. Hultin et al. also disclose adding an organic acid selected from the group consisting of malic, citric, and tartaric acid (p.8/L23-28) after step (b).

Regarding claims 19-21, Hultin et al. disclose all of the claim limitations as set forth above. Hultin et al. also disclose removing the aggregated membrane lipids from the solubilized

protein by centrifugation at from about 5000 x g to 10,000 x g (p.6/L27-29) or by aggregation (i.e. precipitation – p.3/L5-9).

Regarding claims 22-23, Hultin et al. disclose all of the claim limitations as set forth above. Hultin et al. also disclose that the aggregant is selected from the group consisting of carrageenan, algin, demethylated pectin, gum Arabic, chitosan, polyethyleneimine, spermine, spermidine, calcium salt, magnesium salt, sulfate, phosphate, and polyamine (p.8/L8-12).

Regarding claim 27, Hultin et al. disclose all of the claim limitations as set forth above and that the animal muscle is homogenized before adding the polyvalent cation (p.10/L27 - p.11/L2 - Example 1).

Regarding claim 28, Hultin et al. disclose all of the claim limitations as set forth above. Given that calcium or magnesium salts are added to the mixture, step (b), which aggregates the membrane lipids, step (c), it is clear that the steps occur simultaneously (p.8/L8-12).

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

12. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

13. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

14. Claims 10, 16 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hultin et al. (WO 02/20720 A2) as applied to claim 1 above.

Regarding claim 10, Hultin et al. disclose all of the claim limitations as set forth above. While Hultin et al. does not explicitly disclose adding an acid to the mixture for solubilizing the proteins, given that protein will solubilize above and below the isoelectric point, it would have been obvious to one of ordinary skill to have added acid to the mixture to drop the pH below the isoelectric point of the protein and solubilize the protein.

Regarding claim 16, Hultin et al. disclose all of the claim limitations as set forth above. While Hultin et al. disclose incubating the mixture, the reference doesn't explicitly disclose an incubation time. As the extent of aggregation is a variable that can be modified, among others, by adjusting the incubation time, the precise incubation time would have been considered a result effective variable by one having ordinary skill in the art at the time the invention was made. As such, without showing unexpected results, the claimed incubation time cannot be considered

critical. Accordingly, one of ordinary skill in the art at the time the invention was made would have optimized, by routine experimentation, the incubation time of the membrane lipid aggregation disclosed by Hultin et al. to obtain the desired extent of aggregation (*In re Boesch*, 617 F.2d. 272, 205 USPQ 215 (CCPA 1980)), since it has been held that where the general conditions of the claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. (*In re Aller*, 105 USPQ 223).

Regarding claim 26, Hultin et al. disclose all of the claim limitations as set forth above. While Hultin disclose dewatering performed by centrifuging and filtering, the reference does not disclose that dewatering is performed by pressing the mixture. Given that it is pressing is a well known dewatering technique, it would have been obvious to one of ordinary skill in the art to have dewatered the mixture of Hultin et al. by pressing the mixture, because doing so would amount to nothing more than the use of a known dewatering technique for its intended use in a known environment to accomplish entirely expected results.

15. Claims 2 and 14-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hultin et al. (WO 02/20720 A2) as applied to claim 1 above and further in view of Attebery (US 3,560,219).

Regarding claims 2 and 14-15, Hultin et al. disclose all of the claim limitations as set forth above. Hultin et al. fails to disclose that the concentration of calcium or magnesium ions in the mixture are in the range of about 0.1mM to about 50 mM after the addition.

Attebery disclose a process for removing lipid material from an aqueous solution containing protein (C1/L12-17). Attebery teach that 0.075 molal (i.e. approximately 75 mM) of

magnesium chloride or calcium chloride are added to a solution of protein to precipitate and remove the lipid material (C2/L16-47).

Hultin et al. and Attebery are combinable because they are concerned with the same field of endeavor, namely, isolation of proteins by removing undesirable lipid materials. It would have been obvious to one of ordinary skill in the art to have used approximately 75 molal calcium chloride or magnesium chloride, as taught by Attebery, to the muscle protein mixture of Hultin et al., to effectively aid in the removal of lipid material

Further, with regards to claims 14-15, Hultin et al. disclose all of the claim limitations as set forth above but the reference does not explicitly disclose that the polyvalent cations are calcium chloride or magnesium chloride. Given that Hultin et al. disclose calcium and magnesium salts broadly, absent evidence to the contrary, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have used any calcium or magnesium salt, including calcium chloride or magnesium chloride to arrive at the current invention.

Conclusion

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth Gwartney whose telephone number is (571) 270-3874. The examiner can normally be reached on Monday - Thursday;7:30AM - 5:00PM EST, working alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Callie Shosho can be reached on (571) 272-1123. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/E. G./
Examiner, Art Unit 1794

/Callie E. Shosho/
Supervisory Patent Examiner, Art Unit 1794